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*2/10*  
*This discovery request is granted. IBD is directed to produce its Master Formula File for Zylast products, including its concentration and ingredients, as well as any changes or supplements to its concentration over time.*  
**VIA ECF**

The Honorable Paul A. Crotty  
United States District Court  
Southern District of New York  
500 Pearl Street, Chambers 1350  
New York, New York 10007

*The Court did not grant GOJO's letter of 2/13/2016. The Court does not allow sua sponte. All requests are subject to compliance with the Court's rules.*  
*Manuel*  
*Paul Muth*  
**Re: GOJO Industries, Inc. v. Innovative Biodefense, Inc., et al.**  
**Case No. 15-CV-2946 (PAC)**

Dear Judge Crotty:

We represent Plaintiff GOJO Industries, Inc. ("Plaintiff" or "GOJO") and write to seek an order on a discovery issue that had been resolved by the parties, but the resolution has been repudiated by Defendant Innovative BioDefense, Inc. ("IBD"): the production of documents and information regarding the formulas for its Zylast products.

We had raised the issue with the Court as far back as our letter dated September 29, 2015 (Docket # 82). That letter addressed numerous discovery issues, including the request for IBD's formula cards (known at IBD as its Master Formula File), and attached a chart summarizing the outstanding document issues. (Docket # 82-1).<sup>1</sup> The relevance of the formula cards to this case is obvious. There is abundant evidence that IBD has used varying amounts of benzethonium chloride (BZT) in both of its hand sanitizer products over time and that the studies IBD relies upon to support its marketing claims did not test the current formulation of the products.

<sup>1</sup> The table included Request 89 of the Third Request for Documents: "All formula cards for Zylast® products, showing the concentration of all ingredients in Zylast® products."



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GOJO has a right to the formula information to demonstrate that IBD is relying on studies conducted of obsolete formulations of Zylast (and its predecessor, Zytrel) to support claims that Zylast is superior to alcohol-based hand sanitizers, including GOJO's PURELL® products. For example, as noted in our September 29 letter, an IBD witness has testified that the amount of BZT used with alcohol in Zylast Antiseptic is less than the level (0.2%) in the alcohol/BZT product tested in a study IBD uses to claim special efficacy for Zylast Antiseptic.<sup>2</sup>

We did not press the issue regarding outstanding document requests at the November 8 hearing before Your Honor because the parties had made significant progress in resolving discovery disputes. With respect to the formula cards, IBD's counsel came to take the position that IBD objected only to the production of formula cards, but would not oppose discovery of information detailing the formulas of the Zylast products over time.

During the deposition of a GOJO scientist on January 6, IBD's counsel (Mr. Nix) represented: "We don't have a problem giving you the information. It was just formula cards themselves" that IBD did not want to produce.<sup>3</sup> Mr. Nix assured GOJO's counsel (Mr. Skakun) that he would be able to examine IBD's main witnesses on this issue at depositions that would begin January 20. Mr. Skakun asked, "When I come out there in two weeks, your people will

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<sup>2</sup> See Czerwinski et al., "Novel water-based antiseptic lotion demonstrates rapid, broad-spectrum kill compared with alcohol antiseptic," *J. Infect. and Public Health* (2014) 7, 199-204 (abstract attached as Exhibit 1 hereto). The current website of [zylast.com](http://zylast.com) continues to make claims of "Rapid, Broad-Spectrum Kill" for the Zylast Antiseptic and Zylast lotion on the stated basis of that study. Two pages from that website (attached as Exhibit 2 hereto) also make claims on the stated basis of claimed results from a "persistence" study from 2014; two clinical trials on school absenteeism ("Reduces illness outbreaks by 87.5%") and hospital-acquired infections, published in 2013 and 2014 respectively but conducted in prior years (an unpublished version of the hospital study report dates from 2011); and an alleged "on-going" study in 2015. A page on the site also makes the explicit "establishment" claim that "Zylast Antiseptic is the first hand sanitizer proven to reduce hospital-acquired infections ...." (Exhibit 3 hereto.) As with every other study-based claim, the formula of the tested product is plainly relevant to judging that claim.

<sup>3</sup> Excerpt from Transcript of January 6 Deposition of David R. Macinga, at 160 (Exhibit 4 hereto).



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give me the formulas, you will tell me the time periods for which they were being used and what the formula was for that period?" Mr. Nix replied, "Ycah, for the Zylast products, yes."<sup>4</sup> They discussed the matter again on the record on January 7, and Mr. Nix confirmed his commitment.<sup>5</sup>

To be sure, GOJO does not believe that IBD had a reasonable basis for limiting discovery on the formulas to deposition testimony rather than documents, but we were willing to compromise in order to assure that we would obtain the needed evidence on a timely basis. Accordingly, on the basis of Mr. Nix's representations, Mr. Skakun traveled to California to examine the IBD witnesses on this issue. On January 20, however, Mr. Nix blocked his efforts to examine IBD witnesses regarding the formulations of Zylast products over time – the very areas of inquiry he had agreed to on the record two weeks before. Mr. Skakun reminded Mr. Nix of his prior agreement, but he remained adamant that IBD would not answer such questions. Mr. Nix agreed on the record during the deposition that this issue is ready for submission to the Court and no further meet-and-confer efforts are necessary.

Because IBD has repudiated its agreement on discovery, we respectfully request that this Court order IBD to produce not simply testimony but also its Master Formula File for Zylast products, showing the concentrations of all ingredients, including any changes in the ingredients or concentrations of ingredients in these products over time. In addition, because GOJO relied on the representations and commitments of IBD's counsel in incurring the expense of traveling to California for taking depositions of IBD witnesses, GOJO also requests that the Court order

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<sup>4</sup> Id.

<sup>5</sup> Excerpt from Transcript of January 7 Deposition of James W. Arbogast, at 88 (Exhibit 5 hereto).



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IBD to reimburse GOJO its travel costs and its fees in connection with the depositions pursuant  
to Fed. R. Civ. P. 37.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "James D. Arden".

James D. Arden

cc: Mark J. Skakun, Esq.  
Benjamin Nix, Esq.